within ±25 percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over a concentration range from 0.2 to 4.0 mg/m³; and

(2) For intra-shift measurements of less than 8 hours, a 95 percent confidence that the recorded measurements are within ±25 percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over the concentration range equivalent to 0.2 to 4.0 mg/m³ for an 8-hour period.[1]

(c) *Reliability of measurements.* The CPDM shall meet the accuracy requirements under paragraph (b) of this section, regardless of the variation in density, composition, size distribution of respirable coal mine dust particles, and the presence of water spray mist in coal mines.

(d) *Precision.* The precision of the CPDM shall be established through testing to determine the variability of multiple measurements of the same dust concentration, as defined by the relative standard deviation of the distribution of measurements. The relative standard deviation shall be less than 0.1275 without bias for both full-shift measurements of 8 hours or more, and for intra-shift measurements of less than 8 hours within the dust concentration range equivalent to 0.2 to 4.0 mg/m³ for an 8-hour period, as specified under paragraph (b)(2) of this section.

(e) *Bias.* The bias of the CPDM measurements shall be limited such that the uncorrectable discrepancy between the mean of the distribution of measurements and the true dust concentration being measured during testing shall be no greater than 10 percent. Bias must be constant over the range of dust concentration levels tested, 0.2 to 4.0 mg/m³ for an 8-hour sampling period.

(f) *Testing conditions.* Laboratory and mine testing of the CPDM for accuracy, precision, bias, and reliability under diverse environmental conditions (as defined under § 74.7(e) and (g)) shall be determined using the NIOSH testing procedure, ''Continuous Personal Dust Monitor Accuracy Testing,'' June 23, 2008, available at: *http://www.cdc.gov/niosh/mining/pubs/pubreference/outputid3076.htm.* All testing results shall be submitted to NIOSH in writing on the application filed under § 74.11.

(1) Persons must proceed in accordance with NIOSH testing procedure ''Continuous Personal Dust Monitor Accuracy Testing,'' June 23, 2008. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy at the address below: NIOSH–Publications Dissemination, 4676 Columbia Parkway, Cincinnati, OH 45226. *http://www.cdc.gov/niosh/mining.*

(2) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, (202) 693–9440, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 74.9 Quality assurance.

(a) *General requirements.* The applicant shall establish and maintain a quality control system that assures that CPDM devices produced under the applicant's certificate of approval meet the required specifications and are reliable, safe, effective, and otherwise suitable for their intended use. To establish and to maintain an approval under this part, the applicant shall:

(1) Submit a copy of the most recent registration under ISO Q9001–2000,

[1] The equivalent dust concentration range to the 8-hour range of 0.2 − 4 mg/m³ is calculated by multiplying this 8-hour range by the dividend of eight hours divided by the duration of the intrashift measurement specified in units of hours. For example, for a measurement taken at exactly one hour into the shift, the 8-hour equivalent dust concentration range would be a one-hour average concentration range of: 8 hours/1 hour × (0.2 − 4 mg/m³) = 1.6 − 32 mg/m³; for a two-hour measurement, the applicable concentration range would be calculated as: 8 hours/2 hours × (0.2 − 4 mg/m³) = 0.8 − 16 mg/m³; for a 4-hours measurement, the equivalent range would be: 0.4 − 8 mg/m³; * * * *etc.* A CPDM must perform accurately, as specified, for intrashift measurements within such equivalent concentration ranges.

American National Standard, Quality Management Systems-Requirements, published by ISO:

(i) With the application for approval under § 74.13 of this part; and

(ii) Upon request by NIOSH, subsequent to the approval of a CPDM under this part.

(2) Persons must proceed in accordance with ISO Q9001–2000, American National Standard, Quality Management Systems-Requirements. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy from the International Organization for Standardization at the address provided below.

International Organization for Standardization, ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case Postale 56, CH–1211 GENEVA 20, Switzerland. *http://www.standardsinfo.net*.

(3) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, (202) 693–9440, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) *Quality management audits.* Upon request, applicants or approval holders must allow NIOSH to inspect the quality management procedures and records, and to interview any employees who may be knowledgeable of quality management processes associated with the production of the CPDM. Audits may be conducted either on an occasional or periodic basis or in response to quality-related complaints or concerns.

(c) *Applicant remediation of quality management deficiencies.* An applicant or approval holder must correct any quality management deficiency identified by an audit within a reasonable time as determined by NIOSH. Failure to correct a deficiency may result in NIOSH disapproval of a pending application or, in the case of an approved device, revocation of approval until NIOSH determines that the deficiency is corrected.

§ 74.10 Operating and maintenance instructions.

(a) *Contents.* The manufacturer must include operating and storage instructions and a maintenance and service life plan with each new CPDM device sold. These documents must be clearly written.

(1) Operating and storage instructions must include:

(i) An explanation of how the CPDM works;

(ii) A schematic diagram of the CPDM;

(iii) Procedures for wearing and use of the CPDM;

(iv) A one page ''quick start guide'' that will enable a novice to start and operate the CPDM.

(v) Procedures for calibration of the CPDM;

(vi) Procedures for inspecting the operating condition of the CPDM;

(vii) Procedures and conditions for storage, including the identification of any storage conditions that would likely impair the effective functioning of the CPDM; and

(viii) Procedures and conditions of use, including identification of any conditions of use that would likely impair the effective functioning of the CPDM.

(2) The maintenance and service life plan must address:

(i) Conditions that should govern the removal from service of the CPDM; and

(ii) Procedures that a user or others should follow when inspecting, performing maintenance and calibration, and determining when the CPDM should be removed from service.

(b) *Submission to NIOSH for approval.* A copy of the instructions and plan under paragraph (a) of this section shall be submitted to NIOSH with the application for approval of the CPDM and if substantive changes are made to the approved device or approved instructions.

§ 74.11 Tests of the continuous personal dust monitor.

(a) *Applicant testing.* The applicant shall conduct tests to determine whether a CPDM that is submitted for